

DETAILED ACTION

1. This action is in response to the papers filed September 9, 2009. Currently, claims 1-4, 34-39, 42, 43, 47, 49 and 50 are pending. Claims 1-3, 34-39, 42, 49 have been withdrawn as drawn to non-elected subject matter.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 9, 2009 has been entered.
3. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.
4. Any objections and rejections not reiterated below are hereby withdrawn.

Maintained Rejections

Election/Restrictions

5. Applicant's election with traverse of Group II, Claims 4-5, 26, 31, 41, 43-46 in the paper filed June 30, 2008 is acknowledged.

The examiner thanks applicants for pointing out that Claims 43-46 were inadvertently grouped with Group I when they should be grouped with elected Group II. Claims 43-46 are hereby placed in Group II.

Moreover, Claim 31 which depends on Claim 31 is within Group II.

The response further asserts that restriction to a single polymorphism is unduly restrictive. The response asserts that there would not be a serious search and examination burden to the Office and request reconsideration of the restriction requirement to include at least all of the variants to the EMP2B gene identified in the specification. This argument has been reviewed, but is deemed not persuasive. Current Claim 4 appears to be drawn to a generic linking claim. In the event that an allowable generic linking claims is found, the examiner will consider rejoinder of the variants encompassed within the scope of the allowable generic linking claim. However, no allowable generic or linking claim has been presented at this time.

Applicants argue that they are entitled to claim the entire genus of variations of the EPM2B gene that are associated with Lafora's disease. The response states that the members of the genus have a substantial common structure, namely the nucleic acid sequence of EPM2B, as set forth in SEQ ID NO: 1. This argument has been reviewed but is not persuasive. The "substantial common core" is known in the art, namely the "wild type" EPM2B gene is known in the art. It is the differences between the common core that applicants (i.e. the variants) are relying upon for patentability and not the common core structure that was known in the art. Thus, the variants are drawn to what is different from the common core and not the commonality of the core.

Claims 1-3, 6-25, 31, 34-39, 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 1-3, 6-25, 31, 34-39, 42 have drawn to an invention nonelected with traverse in the paper filed June 30, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

6. This application is a 371 of PCT/CA04/01449, July 30, 2004 which claims priority to 60/491,968, filed August 4, 2003.

Information Disclosure Statement

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

a. The specification contains a list on pages 56-60 of the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) It is unclear whether Claim 4 is directed to a method of detecting the presence of or predisposition to Lafora's disease in a human or whether the claim is merely drawn to the detection of a C to G change at nucleotide number 205 in the EPM2B gene sequence comprising SEQ ID NO: 1. The preamble of the claim is directed to detecting the presence of or predisposition to Lafora's disease however the final step is directed to the detection of a C to G change. The claim could be amended to include a wherein clause, for example "wherein the presence of a C to G change at nucleotide number 205 in the EPM2B gene sequence comprising SEQ ID NO: 1 indicates the presence or predisposition to Lafora's disease in the human."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 4, 43, 47, 50 are rejected under 35 U.S.C. 102(a) as being anticipated by Chan et al. (Nature Genetics, Vol. 35, No. 2, pages 125-127, October 2003).

It is noted that the authorship of the Chan et al. reference is distinct from the inventorship of the instant application and that this rejection may be overcome by the filing of a 132 Katz-type declaration.

It is noted that SEQ ID NO: 1 from the provisional application and SEQ ID NO: 1 of the instant application are different. SEQ ID NO: 1 from the provisional application is 2134 nts in length, the instant SEQ ID NO: 1 is 2120. Thus, the instant SEQ ID NO: 1 was not disclosed in the provisional application and the application is awarded priority of the instant filing date.

Chan teaches mutations in the **EPM2B** gene cause Lafora progressive myoclonus epilepsy. Chan teaches screening by sequencing DNA from individuals homozygous with respect to markers in the **EPM2B** critical region (page 125, col. 2). Moreover, Chan teaches sequencing **EPM2B** in a cohort of 34 probands with Lafora disease and identified 17 different DNA sequence alterations in 26 families which were not present in 100 control chromosomes. Among these polymorphisms was the mutation at 205 (see Table 1). Chan teaches that the accession number BK001510 was used for **EPM2B**. This sequence comprises SEQ ID NO: 1 of the instant application, required by the instant claims.

10. Claim 47 is rejected under 35 U.S.C. 102(b) as being anticipated by Blakey et al. (Genbank Number gi13509424, April 30, 2001).

Blakey teaches a DNA sequence from the homo sapiens chromosome 6 clone RP11-204B7 which comprises SEQ ID NO: 1. Blakey teaches detecting the presence of EPM2B gene by analyzing a test sample obtained from the human for the presence of a nucleic acid comprising SEQ ID NO:1.

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Query Match          100.0%; Score 2120; DB 5; Length 147927;
Best Local Similarity 100.0%; Pred. No. 0;
Matches 2120; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      1  ATGGCGSCCGAAGCCTCGGAGACGGGCCACGCGCTGCATGAGCTCATGCGCGAGGCGGAG 60
      |||
Db      85161 ATGGCGSCCGAAGCCTCGGAGACGGGCCACGCGCTGCATGAGCTCATGCGCGAGGCGGAG 85102

Qy      61  ATCAGCCTGCTCGAGTGCAAGGTGTGCTTTGAGAAGTTTGGCCACCGGCAGCAGCGCGCC 120
      |||
Db      85101 ATCAGCCTGCTCGAGTGCAAGGTGTGCTTTGAGAAGTTTGGCCACCGGCAGCAGCGCGCC 85042

Qy      121 CCGGSCAACCTGTCTCGGSCCAGCTGGTCTGCCTGGCCTGCGTGGCGGCGCTGGCGGAC 180
      |||
Db      85041 CCGGSCAACCTGTCTCGGSCCAGCTGGTCTGCCTGGCCTGCGTGGCGGCGCTGGCGGAC 84982

Qy      181 CCGGSCACTCTGGGCCCTCGAGTGCCCAATTCTGCAGGCGAGCTTGC GGCGGCTGCGACACC 240
      |||
Db      84981 CCGGSCACTCTGGGCCCTCGAGTGCCCAATTCTGCAGGCGAGCTTGC GGCGGCTGCGACACC 84922

Qy      241 AGCGACTGCCTGCCGGTGTGCACTCATAGAGCTCCTGGGCTCAGCGCTTCGCCAGTCC 300
      |||
Db      84921 AGCGACTGCCTGCCGGTGTGCACTCATAGAGCTCCTGGGCTCAGCGCTTCGCCAGTCC 84862

Qy      301 CCGGCGCGCCATCGGCGCGCGCCCGAGCGCGCGCGGAGCGCTCACTGCCACCAACCTTC 360
      |||
Db      84861 CCGGCGCGCCATCGGCGCGCGCCCGAGCGCGCGGAGCGCTCACTGCCACCAACCTTC 84802

Qy      361 GCGGCGCTGGGGGACCTTGSTCAACCCACCGGACTGGCGCTTTGTCCCAAGACGGGGCGT 420
      |||
Db      84801 GCGGCGCTGGGGGACCTTGSTCAACCCACCGGACTGGCGCTTTGTCCCAAGACGGGGCGT 84742

Qy      421 GTGCTGTTGGTGCACGACGSCAGGAGGCGTGTCAAGATTTTGTACTCAGGGGGAGGATGC 480
      |||
Db      84741 GTGCTGTTGGTGCACGACGSCAGGAGGCGTGTCAAGATTTTGTACTCAGGGGGAGGATGC 84682

Qy      481 GCGCATCAGTTTGGAGAGAAGGGGGACGCTGCCCAAGACATTAGTACCTGTGGATGTC 540
      |||
Db      84681 GCGCATCAGTTTGGAGAGAAGGGGGACGCTGCCCAAGACATTAGTACCTGTGGATGTC 84622

Qy      541 ACCATCACCAAGACTGCCATGTGGTTGTCACTGACGCGCGGATCGCTCCATCAAAAGTG 600
      |||
Db      84621 ACCATCACCAAGACTGCCATGTGGTTGTCACTGACGCGCGGATCGCTCCATCAAAAGTG 84562

Qy      601 TTTGATTTTTTTGGCAGATCAAGCTTGTCACTGGAGGCGCAATTCCTCTACCTTGGGGT 660
      |||
Db      84561 TTTGATTTTTTTGGCAGATCAAGCTTGTCACTGGAGGCGCAATTCCTCTACCTTGGGGT 84502

Qy      661 GTGGAGACCAACCCCTCAGAAATGGGATTGTGTTAACTGATCGGAGGCGAGGGTCCCTGCAC 720
      |||
Db      84501 GTGGAGACCAACCCCTCAGAAATGGGATTGTGTTAACTGATCGGAGGCGAGGGTCCCTGCAC 84442

Qy      721 CTCCTGACCTCGACTTCGCGGGAAGGGTTCCTTCGGAGAAGTCAAAGTTGCAAGCTCAT 780
      |||
Db      84441 CTCCTGACCTCGACTTCGCGGGAAGGGTTCCTTCGGAGAAGTCAAAGTTGCAAGCTCAT 84382
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Qy	781	CTGTGCAATCCCCGAGGGGTGGCAGTGTCTTGGGCTCACCGGGGCCATTGCGGTCTCTGGAG	840
Db	84381	CTGTGCAATCCCCGAGGGGTGGCAGTGTCTTGGGCTCACCGGGGCCATTGCGGTCTCTGGAG	84322
Qy	841	CACCCCCCTGGCCCTGGGACTTGGGGTTTGCAGCACCAGGGTGAAAGTGTTTAGCTCAAGT	900
Db	84321	CACCCCCCTGGCCCTGGGACTTGGGGTTTGCAGCACCAGGGTGAAAGTGTTTAGCTCAAGT	84262
Qy	901	ATGCAGCTTTGCGGCCAAGTGGATACCTTTGGGCTGAGGCTCTACTTTCCTCCAAAATA	960
Db	84261	ATGCAGCTTTGCGGCCAAGTGGATACCTTTGGGCTGAGGCTCTACTTTCCTCCAAAATA	84202
Qy	961	ACTGCTCCGCTGTGACCTTTGATCACCAGGGAATGTGATTGTCAGATACATCTGTT	1020
Db	84201	ACTGCTCCGCTGTGACCTTTGATCACCAGGGAATGTGATTGTCAGATACATCTGTT	84142
Qy	1021	CCAGCTATCCTTTGCTTAGGAAAACCTGAGGAGTTTCCAGTACCGAAGGCCATGTCAC	1080
Db	84141	CCAGCTATCCTTTGCTTAGGAAAACCTGAGGAGTTTCCAGTACCGAAGGCCATGTCAC	84082
Qy	1081	CATGCTCTTTGCGCATCCTGTGGCTCTTACCTTCACCAAGGAGAAATCTCTTCTTGTGCTG	1140
Db	84081	CATGCTCTTTGCGCATCCTGTGGCTCTTACCTTCACCAAGGAGAAATCTCTTCTTGTGCTG	84022
Qy	1141	GACACAGCATCTCATTTCTATAAAAGTCTATAAAAGTTGACTGGGGGTGATGGGCTGGGGTG	1200
Db	84021	GACACAGCATCTCATTTCTATAAAAGTCTATAAAAGTTGACTGGGGGTGATGGGCTGGGGTG	83962
Qy	1201	GCTCCCTGGAATCAGAAGCACTAGTGTGCCATTAAATGAATTTGTTAAACCTGGATAGT	1260
Db	83961	GCTCCCTGGAATCAGAAGCACTAGTGTGCCATTAAATGAATTTGTTAAACCTGGATAGT	83902
Qy	1261	CACCTAAACTCATCTATCCAGGCGAGGATAAATAAAACCATCTGGCAGACTTACAAAAGT	1320
Db	83901	CACCTAAACTCATCTATCCAGGCGAGGATAAATAAAACCATCTGGCAGACTTACAAAAGT	83842
Qy	1321	TGGGACAGTATTGAGAGTTAATCTACCAATTTATTGAATGCATACCTGTGCGCAAGGAAAT	1380
Db	83841	TGGGACAGTATTGAGAGTTAATCTACCAATTTATTGAATGCATACCTGTGCGCAAGGAAAT	83782
Qy	1381	TTGCAAAATATTAGCTTATTTAATCTGTACTATCCAGTGAGGTAAATTTCTCCCCCGCAAG	1440
Db	83781	TTGCAAAATATTAGCTTATTTAATCTGTACTATCCAGTGAGGTAAATTTCTCCCCCGCAAG	83722
Qy	1441	ATAGAGTCAAGCTCTGTGACCCAGGCTGAGTGCAAGCATGATCAGAGCTCACTACAG	1500
Db	83721	ATAGAGTCAAGCTCTGTGACCCAGGCTGAGTGCAAGCATGATCAGAGCTCACTACAG	83662
Qy	1501	TTTCAACGTCCCCCGCTCAGGTGGTCTCTTCCACCTCAGGCTCCCAAGTAGTGGGACCAC	1560
Db	83661	TTTCAACGTCCCCCGCTCAGGTGGTCTCTTCCACCTCAGGCTCCCAAGTAGTGGGACCAC	83602
Qy	1561	AAGTGTGCATTACCACTACAGCTAATTTTGTATTTTGGCAGAGATGGGGTTTCACCAT	1620
Db	83601	AAGTGTGCATTACCACTACAGCTAATTTTGTATTTTGGCAGAGATGGGGTTTCACCAT	83542
Qy	1621	GTTGCCGAGGCTGGTCTCAAACTCTCGAGTTCAAGCAATCCACCTTCTCGGGCTCCCAA	1680
Db	83541	GTTGCCGAGGCTGGTCTCAAACTCTCGAGTTCAAGCAATCCACCTTCTCGGGCTCCCAA	83482
Qy	1681	AGTACTAGGAGTACAGGCATAGCCACTTGTCTCAGCCATATTTTATTATTAAATCTCAAT	1740
Db	83481	AGTACTAGGAGTACAGGCATAGCCACTTGTCTCAGCCATATTTTATTATTAAATCTCAAT	83422
Qy	1741	GTCAAGTGAGAAAACCTGAGACCCAGAGAGCTTAAGTGAATCTTCTCGAGGCTCATAGTAC	1800

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Db	83421	GTACAAATCGAGAAAACCTGAGACCCAGAGAGCCTTAAGTGACTTCCTCGAGGTGATAGTTAC	83362
Qy	1801	TTACTGCGTTAGTCCCAATTTCGAATTCAACTCTGATTCGCAAAATAGTTGCGCTTAAATAA	1860
Db	83361	TTACTGCGTTAGTCCCAATTTCGAATTCCTGATTCGCAAAATAGTTGCGCTTAAATAA	83302
Qy	1861	GACACACAGATGGGAGAAAATAATGCTGAATGTGATGCTGCTGCTGCTGCTGCTTACA	1920
Db	83301	GACACACAGATGGGAGAAAATAATGCTGAATGTGATGCTGCTGCTGCTGCTGCTTACA	83242
Qy	1921	AGTAGCTAATTATTTTAGACACAAGATGTGCAAAAGAGAGACGCTTATGGAGAGTTCAG	1980
Db	83241	AGTAGCTAATTATTTTAGACACAAGATGTGCAAAAGAGAGACGCTTATGGAGAGTTCAG	83182
Qy	1981	GACAAAAAGAGATTTTGTGGTGGCCATCAGCTTTCATTCAATTTGCGACTGCTGTATGCGA	2040
Db	83181	GACAAAAAGAGATTTTGTGGTGGCCATCAGCTTTCATTCAATTTGCGACTGCTGTATGCGA	83122
Qy	2041	CATTAGATGAAGTTACTGTTGATCCTGAGTTACGTGAATAGAAAAACAATTGAAGTGT	2100
Db	83121	CATTAGATGAAGTTACTGTTGATCCTGAGTTACGTGAATAGAAAAACAATTGAAGTGT	83062
Qy	2101	TATTAAAAAGTAAATATGT	2120
Db	83061	TATTAAAAAGTAAATATGT	83042

Conclusion

11. No claims allowable.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, can be reached on (571)272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

/Jeanine Goldberg/

Primary Examiner

November 25, 2009